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09/912,499	07/26/2001	David Hung	05284.00096	6261

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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/912,499
Filing Date: July 26, 2001
Appellant(s): HUNG, DAVID

Theodore R. Allen, Cytyc Corporation
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 15 February 2006 appealing from the Office action mailed 15 August 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,616,656	NICHOLSON et al.	10-1986
4,767,011	BUTLER	08-1988
4,947,842	MARCHOSKY et al.	08-1990
5,003,905	RAYNOR	04-1991
5,623,942	PESTES et al.	04-1997
6,101,635	JONES	08-2000
6,319,267	KURZ	11-2001
6,391,026	HUNG et al.	05-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,623,942 to Pestes et al. (hereinafter "Pestes").

Pestes discloses a flexible probe 12 having a diameter that is sized to access a breast duct and a distal portion being capable of contacting an interior lumen of a breast duct and retrieving a sample of the breast duct fluid from within the duct for analysis (distal end of 10), and wherein said probe is free of an opening through which a fluid from an external source can be introduced into said probe and pass through said probe into the duct when said probe is positioned within the breast duct (Fig. 1), and wherein said probe is rigid before entry into the breast duct, and flexible upon resistance into the duct (col. 2, lines 16-25 and 32-40); as to claims 2-6, (distal end of 10). As to claim 13, (nylon).

In support of the Examiner's position that Pestes discloses a flexible probe having a diameter that is sized to access a breast duct and a distal portion that is capable of contacting an interior lumen of a breast duct, the Examiner relies on the disclosure of U.S. Patent No. 6,391,026 to Hung et al. (hereinafter "Hung"). Hung discloses a catheter that is used to access a breast duct having an outer diameter of 0.8 mm (or 0.08 cm). See Figures 1-10B and col. 10, lines 54-63. Here, Pestes discloses a device that is capable accessing a breast duct that has an outer diameter of 0.035 inches (or 0.08 cm). Therefore, the Pestes device is capable of performing the function as set forth in claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7, 8, 10, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pestes in view of U.S. Patent No. 4,616,656 to Nicholson et al. (hereinafter "Nicholson").

Pestes discloses a device for collecting breast duct fluid substantially as claimed except for a means (marker/indicia) to measure a quality of the ductal fluid *in situ*. Nicholson discloses a means (marker/indicia) to measure a quality of the ductal fluid *in situ* (col. 4, lines 12-17). Therefore, It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the distal portion of Pestes with the mans to measure a quality of the ductal fluid, as taught by Nicholson, for providing markings to indicate the depth of the device distal end when anchored. It is noted that Appellant indicates that such quality/means can comprise a marker (page 4, line 8).

Pestes discloses a device for collecting breast duct fluid substantially as claimed except for a probe diameter between 0.008 cm to about 0.045 cm. Pestes discloses a probe with a diameter of 0.08 cm. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to vary the diameter of the probe, since it would only involve a mere change in the size of a component. Additionally, Appellant has not disclosed that a diameter between 0.008 cm to about 0.045 cm provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Appellant's invention to perform equally well with a diameter of 0.08 cm. Therefore, such a change in size is considered to be well within the level of skill of the ordinary artisan.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pestes in view of U.S. Patent No. 4,947,842 to Marchosky et al. (hereinafter "Marchosky").

Pestes discloses the device substantially as claimed except for a coating of an anesthetic on the exterior of the probe. Marchosky discloses an anesthetic coating on the exterior of the probe. Therefore, It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Pestes with the coating taught by Marchosky to relieve pain in the treatment of tumors particularly in the breast area (col. 5).

(10) Response to Argument

a. Pestes discloses every single element of independent claim 1.

In response to Appellant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a probe that is sufficiently rigid to enter through the sphincter of a breast duct, but flexible enough that the body will bend when it encounters resistance within the breast duct [Appeal Brief, p. 5, lines 2-5]) are not recited in the rejected claim(s). The claim language does not specify the degree of rigidity or flexibility that the Appellant suggests in the Appeal Brief. If the probe should be rigid enough to pass through a closed sphincter of a breast duct as opposed to one that is already opened or malfunctioning, then the claim language should specify such a limitation. Otherwise, such a limitation will not be read into the claims. The same argument is applicable to the flexibility of the probe. Appellant does not claim that the probe should be flexible enough that it will bend upon reaching a branch in the ductal passageway. The claim does not specify what type of resistance that the probe will encounter once inside the passageway (e.g. the wall of a normal

ductal passageway, the wall of a hardened ductal passageway, a lesion within the wall of the passageway (e.g. papilloma)). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

For these reasons, Pestes anticipates independent claim 1, and the rejection under 35 U.S.C. §102(b) must be sustained.

b. Pestes discloses the limitations of claim 13.

Appellant's claim 13 requires that the probe is made of a shape memory material. Pestes suggests fiberglass and nylon as materials for the probe. Fiberglass and nylon can be considered as shape memory materials. All that is required for something to have shape memory characteristics is the ability to return to its original shape when an external force that flexes the object, is removed. For example, a rod made of fiberglass or nylon will flex when a force is applied perpendicular to the length of the rod. When the force is removed, the rod will return to its original shape. U.S. Patent Nos. 4,767,011 to Butler and 5,003,905 to Raynor provide evidence that fiberglass may be manufactured to be highly flexible or rigid. U.S. Patent Nos. 6,101,635 to Jones and 6,319,267 to Kurz provide evidence that nylon may be manufacture to be highly flexible or rigid. These ranges of flexibility or rigidity of fiberglass and nylon show that devices may be manufactured to a sufficient rigidity such that it would exhibit shape memory qualities.

For these reasons, Pestes anticipates dependent claim 13, and the rejection under 35 U.S.C. §102(b) must be sustained.

c. The elements of claims 7, 8 and 10 are obvious over Pestes in view of Nicholson.

Appellant argues that Nicholson does not disclose a means to measure the quality of the ductal fluid. Claim 8, which is dependent from Claim 7, requires that a quality indicia is cell size. The markings provided by Nicholson are used to measure the depth of a breast lesion via mammogram. It is also possible that these markings provide a scale to measure an individual cell size. If cell size is an indicator of a quality of ductal fluid as suggested by Appellant's claim 8, then markings suggested by Nicholson is certainly a means to measure a qualitative aspect of ductal fluid.

For these reasons, claims 7, 8 and 10 are unpatentable over Pestes in view of Nicholson. The rejection under 35 U.S.C. §103(a) must be sustained.

d. The elements of claims 26 and 27 are obvious over Pestes.

In response to Appellant's argument that the Pestes reference is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the Pestes reference is in the field of devices used to collect fluid/cell samples. The only difference is in the location of where the samples are retrieved. A mere change in the size of a device to access a different area of the body is obvious to one of ordinary skill in the art and is unpatentable over Pestes.

For these reasons, claims 26 and 27 are unpatentable over Pestes. The rejection under 35 U.S.C. §103(a) must be sustained.

e. The elements of claim 11 are obvious over Pestes in view of Marchosky.

In response to Appellant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Marchosky discloses that tumor treatment can be painful when being accessed by a probe in a sensitive area such as the breast. See Marchosky, col. 5, lines 35-37. Marchosky suggests the use of an anesthetic on the exterior of a probe to help relieve the pain. The Pestes probe is being used to collect samples from sensitive areas of the body and would benefit from the use of an anesthetic on the exterior of the probe. Such a combination would not destroy the function of the Pestes probe and would be used for the same purpose as Marchosky intended.

For these reasons, claim 11 is unpatentable over Pestes in view of Marchosky. The rejection under 35 U.S.C. §103(a) must be sustained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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